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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WORTMAN, DONNA C

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/29/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/147,801

Applicant(s)

NIKlasson, BO

Examiner

Donna C. Wortman, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9,11 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,7,9,11 and 15-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,7,9,11 and 15-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The request filed on July 3, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/147801 is acceptable and a CPA has been established. An action on the CPA follows.

This application is still not in complete compliance with the sequence rules. In particular, it does not comply with 37 CFR 1.821(d) which requires that all sequences embedded in the specification be accompanied by the appropriate sequence identifier. There are sequences at least at pages 6 and 7 that are not accompanied by a SEQUENCE ID NO. There may be others as well. Applicant is given the same time to comply with the sequence rules as is available to reply to this action.

Claims 4, 7, 9, 11, and 15-19 are under examination. Claims 1-3 and 5 remain pending but withdrawn from examination as drawn to a non-elected invention.

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 fails to further limit the subject matter of claim 16, insofar as claim 16 depends from claim 18, which recites a subunit of a virus, and claim 16 is drawn to an embodiment reciting a vaccine additionally comprising a subunit of a virus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 7, 9, 11, and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 11, and 16 are indefinite in reciting "homologous sequences having at least 75% homology to SEQ ID NO: ..." essentially for reasons of record in rejecting claims in the Office action mailed December 15, 2000, as Paper No. 14. In particular, the specification does not define either "homologous sequences" or "homology" in such a way that one of skill in the art could reasonably determine what Applicant intends by the cited terminology.

Applicant has previously argued that the specification states that the "amino acid homology in the non-coding region of different picornavirus isolates was established by screening the entire Swiss Protein Data Bank using the BLITZ search algorithm with standard search parameters" and also states that "the BLITZ search algorithm takes into account identical as well as similar amino acids" so that one skilled in the art would understand what is meant by "homologous sequence" or "homology" in the claims.

This argument has been considered but not found persuasive. With respect to claim 16, which recites "homologous" in the context of a non-coding region of nucleotide sequence, Applicant's argument as directed to amino acid sequence is not understood and is not seen to apply. With respect to claim 4, which recites "homologous sequences having at least 75% homology to the SEQ ID NO:4," taking into account Applicant's apparent reliance on the default parameters of the BLITZ software as a definition of "75% homology," it is still not apparent what combination of identical and

"similar" amino acids is being claimed, and it is not clear what type of similarity is required in order to be encompassed by the claims. Homology determined by considering "similarity" does not render the claims definite without definition of kind and degree of similarity required or intended. Neither homology nor similarity is described or defined in the instant specification in such a way that one of skill in the art can unambiguously determine the metes and bounds of the claims.

Claim 17 is confusing as it depends from claim 4 and recites "comprising an antigen" since it is not clear whether the "antigen" is the same as the "antigenic fragment" of claim 4 or some additional, undefined, component.

Claims 7, 11, 15, and 16 are confusing because each depends alternatively from claims 4 and 17 and recites "an antibody-binding part" of a protein; it is not clear whether the cited material is the same as the "antigenic fragment" of claim 4 or the "antigen" of claim 17. If all these terms are intended to mean different things, Applicant is requested to point out the differences. If they are intended to mean the same thing, consistent terminology should be used throughout the claims in order to avoid confusion.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7, 9, 11, and 15-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein SEQ ID NO:4 does not

enable a protein having at least 75% homology to SEQ ID NO:4, or an antigenic or antibody-binding portion of SEQ ID NO:4, nor an antigenic or antibody-binding portion of a protein having at least 75% homology to SEQ ID NO:4, nor a viral subunit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. With respect to claim 4, the terms "homologous" and "homology" are indefinite as discussed above. The specification does not teach how to make and use proteins that are in some sense "homologous" to SEQ ID NO:4 since no "homologous" proteins are disclosed. Even if "homologous" is taken in a more restrictive sense to mean "identical," the specification does not provide disclosure that is commensurate in scope with the claim, since it does not disclose proteins comprising amino acid sequences that are at least 75% identical to SEQ ID NO:4 and does not teach how to, or provide guidance as to how to obtain, make, and/or use such proteins. Further, the specification does not teach which "fragments" of the protein are antigenic, nor which portions are "antibody-binding," nor does it teach how to make and use antigenic fragments, since it does not identify which portions of a protein that comprises SEQ ID NO:4 would be expected to raise antibodies that would be diagnostic, protective, or therapeutic. With respect to claims 16 and 19, the specification does not teach how to identify or isolate a viral subunit.

Applicant has argued that as the application as filed refers to at least one algorithm (BLITZ) for determining amino acid sequence homology, one of ordinary skill

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in the art would readily be able to make and use proteins at least 75% homologous in amino acid sequence to SEQ ID NO:4 without undue experimentation.

This argument has been considered but not found persuasive. Without further guidance as to what proteins would have 75% homology, to SEQ ID NO:4, given the different types of amino acid similarity/homology included, it would require undue experimentation even to identify all the proteins that are encompassed by the claim in order to make the claimed invention. Further, there is no guidance as to which of the myriads of possible sequences and proteins included would function as required in order that one of skill in the art would know how to use all the proteins encompassed by the claims.

Applicant has previously argued that the amended claims now recite a protein comprising an antigen and that the application as filed teaches a method for determining if a protein or a fragment is antigenic and cites specification page 4, line 30, to page 5, line 14, as describing such a method.

This argument has been considered but not found persuasive. The specification at page 4, line 30, to page 5, line 14, describes immunization of mice with a cell culture supernatant and subsequent indirect immunofluorescence test using a preparation of infected cells to detect antibodies produced by the immunization and does not teach how to determine antigenic fragments of a protein comprising SEQ ID NO:4 or sequences homologous to SEQ ID NO:4.

Claims 15, 18, 9, 11, 16 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, essentially for reasons of record. In particular, the specification does not provide factual evidence that any known diseases or pathological conditions, human or animal, are actually caused by the Ljungan virus which was isolated from rodents. Niklasson et al. (Virology 255:86-93, 1999), of record, published well after the foreign priority date of the instant application, state that, although the goal of the reported study was to find new etiologic agents causing myocarditis in humans, "... thus far we have been unable to demonstrate a pathogenetic role of the Ljungan virus isolates as the causative agents of human disease ..." (page 90, first full paragraph in col. 1). Based on the state of the art at the time the invention was made, the lack of working examples in the specification, and the lack of evidence that any diseases or conditions are associated with the virus from which a protein comprising SEQ ID NO:4 was identified, much less that any beneficial effect would be obtained by administering the protein to a mammal, including a human, the specification cannot be said to enable one of skill in the art to make and use the invention with respect to vaccines or treatments for diseases caused by a Ljungan virus.

With respect to claims drawn to pharmaceutical compositions, vaccines and methods of use, Applicant has previously argued that the application as filed provides factual evidence of human infection by a virus of the invention and points to page 14, lines 1-28, describing human sera containing antibodies specific for "the viral proteins of the invention," as well as to page 3, lines 4-11, describing similar viruses; and has cited Jun et al., Dan et al., and Tolbert et al., all cited on PTO 1449, as describing murine

infections with picornaviruses that are associated with diseases or pathological conditions.

These arguments have been considered but not found persuasive. The specification at page 14, lines 1-28, disclose that antibodies present in human sera from patients disclosed as having diabetes mellitus or myocarditis immunoreact with certain viral-infected African green monkey kidney cells. It is not even apparent that the antibodies detected are specific for the protein that is recited in the instant claims, and there is no evidence that any disease is actually caused by the Ljungan virus. Further, there is no factual evidence that would indicate that administration of the protein that comprises the amino acid of SEQ ID NO:4 and/or a subunit of the virus from which the recited sequences originate would have any beneficial effect for any mammal, including humans, although such use is encompassed by the claims. The documents cited by Applicant do not disclose any information concerning the Ljungan virus but rather are concerned with other, different, picornaviruses.

A claim limited to a protein comprising SEQ ID NO:4 would be allowable as previously indicated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
July 26, 2002